

UNITED STAT. DEPARTMENT OF COMMERCE

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FIRST NAMED INVENTOR APPLICATION NO. FILING DATE ATTORNEY DOCKET NO.

09/443,986

11/19/99

OMAHONY

13

99.1064.US

HM22/1020

MARY L SEVERSON PH.D. ESQ ELAN PHARMACEUTICAL RESEACH CORP 1300 GOULD DRIVE GAINESVILLE GA 30504

ANDRES.J **ART UNIT** PAPER NUMBER 2 1646

EXAMINER

DATE MAILED:

10/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

	Application No.	Applicant(s)
Office Action Summary	09/443,986	OMAHONY, DANIEL JOSEPH
	Examiner	Art Unit
	Janet L Andres	1646
The MAILING DATE of this communication appe	ars on the cover sheet with the co	prrespondence address
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE $\underline{1}$ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
 Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Status 		
1) Responsive to communication(s) filed on		
2a) This action is FINAL . 2b) This action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		•
4)⊠ Claim(s) <u>1-43</u> is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6) Claim(s) is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claims 1-43 are subject to restriction and/or election requirement.		
Application Papers		
9) The specification is objected to by the Examiner.		
10) The drawing(s) filed on is/are objected to by the Examiner.		
11) The proposed drawing correction filed on is: a) approved b) disapproved.		
12) The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. § 119		
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).		
a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:		
1. received.		
2. received in Application No. (Series Code / Serial Number)		
3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).		
* See the attached detailed Office action for a list of the certified copies not received.		
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).		
Attachment(s)		
 15) Notice of References Cited (PTO-892) 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 	19) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-17, 27, 30-34, and 40-43, drawn to peptides and compositions, classified in class 530, subclass 300.
- II. Claims 18-26 and 35-39, drawn to methods of delivery and treatment, classified in class 514, subclass 2.
- III. Claims 28 and 29, drawn to antibodies, classified in class 530, subclasses 388.1 and 389.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptides can be used for other purposes, such as the generation of antibodies.

Inventions I and III are distinct from each other because they are chemically and physically distinct entities. Further, while the peptides of Invention I can be used to generate the antibodies of Invention III, they have other uses, such as receptor binding.

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Inventions II and III are unrelated. The antibodies of Invention III can not be used in the methods of Invention III.

Because these inventions are distinct for the reasons given above and different searches are required for the different groups, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: ZElan 144, ZElan 145, and ZElan 146.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D. October 11, 2000

YNWYL CYUL) YVONNE EYLER, PH.D PRIMARY EXAMINER